## BioGenerix AG

## Claims

- 1. A stable pharmaceutical formulation of erythropoietin containing tris-(hydroxymethyl)-aminomethane as stabilizer, whereby the formulation does not contain amino acids or human serumalbumin.
- 2. A stable pharmaceutical formulation of claim 1 comprising:
- a) as a pH buffering agent a sodium phosphate buffer,
- b) as stabilizer tris-(hydroxymethyl)-aminomethane in an amount of 10 to 200 mM and/or NaCl in an amount of 20-150 mM,
- c) a pharmaceutical quantity of erythropoietin,
- 3. The formulation of claim 1 or 2 which is an aqueous formulation.
- 4. The formulation of any of the preceding claims wherein the pH buffering agent has the formula  $Na_xH_yPO_4$  wherein x is 1 or 2 and y is 1 or 2 and the sum of x and y is 3 whereby the pH buffering agent is present in the pharmaceutical formulation in a range of 5 mM to 50 mM.
- 5. The formulation of any of the preceding claims wherein the pH ranges from 5.9 to 6.8, preferably from 6.2 to 6.6.
- 6. The formulation of any of the preceding claims wherein the tris-(hydroxymethyl)-aminomethane is present in an amount of 20 to 100 mM.
- 7. The formulation of any of the preceding claims which comtains also a non-ionic detergent in an amount ranging from 0.005 to 0.1 % w/v.

WO 2005/053745 PCT/EP2004/013619

10

- 8. The formulation of claim 7 wherein the non-ionic detergent is a polysorbate, preferably Tween 20 or Tween 80.
- 9. The formulation according to claim 8 wherein the polysorbate is not produced from materials derived from animals and wherein the content of peroxide is lower than  $1.00 \mu mol/g$ .
- 10. The formulation according to any of the preceding claims wherein the amount of NaCl ranges from 50 to 100 mM.
- 11. The formulation according to any of the preceding claims which comprises further ethylenediaminetetraacetic acid in an amount of 0.1 to 0.5 mM.